

PROTOCOL TITLE: Administration Method of Cognitive Screening in Older Individuals With Hearing Loss

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1.0 Purpose of the study:

The objectives of the current project are to determine whether a more controlled amplification method or a visual administration can affect cognitive test scores in older individuals with hearing loss.

2.0 Background / Literature Review / Rationale for the study:

Hearing loss and mild cognitive impairment are two health conditions that are highly prevalent in the older cohort [1-4]. As a consequence, many older individuals who seek health care may have untreated hearing loss and undiagnosed cognitive disorders. While there is epidemiological evidence that hearing loss is associated with cognitive decline and dementia [5,6], it has also been argued that disregarding the impact of hearing loss on cognitive testing results may contribute to an inflated rate of cognitive decline [7].

Previous research evidence has shown that removing test items that heavily rely on auditory processing has a significant effect on cognitive scores [8]. Data from studies with listeners with simulated hearing loss [9] or mild-moderate hearing loss [10] converge to demonstrate the negative impact of hearing loss on cognitive performance. Use of hearing aids or personal amplification, albeit aids speech recognition, does not improve the score of cognitive testing [10]. As the listeners in the previous study used their own hearing aids, the implementation of amplification was less controlled, and therefore could introduce variability in sound level and quality. Depending on the processing strategy, potential adverse signal factors may offset the benefit from improved audibility, with the consequence of worse performance on a cognitive measure. According to this hypothesis, a more controlled amplification method or a visual administration that does not rely on auditory processing may improve test scores from older individuals who have hearing loss.

The objectives of the current project aim to determine whether a more controlled amplification method or a visual administration has an effect on hearing impaired older individuals' cognitive test scores.

Aim 1 is to create a visually administered condition of a cognitive test and to validate this condition in comparison to the auditory administration. Data will be collected from younger individuals with

normal hearing. Each younger individual is tested using both visual and auditory condition and the scores are compared across the two conditions. It is anticipated that the scores will not be significantly different between the two conditions. Any remaining difference in performance will be used for analyzing the data from older participant with hearing loss.

Aim 2 is to examine the test condition effect on cognitive testing results in older individuals with hearing loss. The three test conditions include auditory unamplified, auditory amplified, and visual. Each older individual will be tested using two different test conditions. It is predicted the auditory amplified and visual administrations will alleviate the cognitive load associated with hearing difficulty and lead to improved performance on the test.

In addition, three measures are also collected in this protocol for the purposes listed below.

- 1) Speech recognition score: to ensure the improvement in audibility by amplification [10].
- 2) Auditory and visual working memory measures: to account for individual variability in responding to a visual task, as compared to an auditory task [11].
- 3) Social participation surveys: to partially elucidate the connection between hearing and cognitive abilities [12].

3.0 Inclusion and Exclusion Criteria:

All individuals will receive a hearing test to determine current hearing status and a vision test to verify participants can read all computer displays. Older adults will also receive a cognitive test (DRS-II [13]) to screen for moderate to severe cognitive impairment.

Inclusion criteria:

Younger control group: 13 adults aged 18-35 with normal hearing. Three older groups, each with 8 adults aged 60-85 with mild-moderate sensorineural hearing loss: Group1 (Amplified-Visual), Group2 (Amplified-Unamplified), Group3 (Amplified-Unamplified). All participants will have normal or corrected-to-normal vision.

Younger control group will be tested in Experiment 1 (Aim 1) for validating the visually administered cognitive test and for measuring any difference in performance across two

testing conditions (visual vs. auditory). Only younger participants with normal hearing are included to minimize the impact of individual variability in cognitive and hearing abilities. The age range of 18-35 is determined based on cognitive aging literature [23], which indicate minimum changes in cognitive ability within this age range.

Older Group 1-3 will be tested in Experiment 2 (Aim 2) for examining the test modality effect on older individuals with hearing loss and for determining the impact of amplification on cognitive performance. The age range of 60-85 is again defined by the literature [23] that shows a rapid change of cognitive performance in this age range. Older adults who are above 85 years old are not included due to an increased prevalence of dementia [24].

Exclusion criteria:

Adults with conductive hearing loss; history of otologic or neurologic disorders, children (<18 years) and adults >85years; adults who fail the dementia screening test (DRS-II score < 124 [14]); adults who are non- English speaking, or non-native English speaking.

No special populations will be enrolled in the study (e.g.: adults unable to consent, minors, or prisoners).

4.0 Research Locations:

This research will be conducted in Hearing Aid Laboratory (Frances Searle Building 1-451) on the Evanston Campus of Northwestern University.

5.0 Procedures Involved:

Experiment 1: one group of younger participants (n=13), who will only be tested in one session. Each participant will receive both test conditions (visual and auditory unamplified) for cognitive test and speech recognition tests. The assignment of the test versions is randomized.

Procedures (duration: 2 hours)

Hearing and vision screenings (Test 1 and 2) are screening procedures used for determining the eligibility of the participant. If the participant fails the screening, he/she will be informed

immediately at the end of the screening. No research data will be collected after that point. They will not be compensated for the time they have spent on screening tests. If subjects provide authorization, the lab will keep contact information and screening results via the optional element of the consent. However, if they do not provide this authorization, their screening results, and identifiable information will be destroyed.

1. Hearing tests
 - 1) Case history: Participants will be asked questions about their hearing and health history.
 - 2) Otoscope exam: Participants will undergo a brief evaluation of their ear and ear canal with an otoscope.
 - 3) Hearing test. All subjects will undergo hearing testing, where soft tones are presented through earphones and the subject is asked to respond whether s/he has heard the tone by pressing a button. This is a standard clinical test.
2. A vision screening will be administered using a Snellen chart to verify the participant can read all computer displays.
3. Cognitive test. The two versions of Montreal Cognitive Assessment (MoCA) [16] will be used to create 4 test conditions (Version A- Auditory unamplified, Version A-Visual, Version B-Auditory unamplified, Version B-Visual). Each participant will receive two administrations, with a different test version and counterbalanced testing order.
4. Word recognition: NU-6 Word List. Two word lists of 50 words will be presented to the participants, one visually and one aurally. The participant will be instructed to repeat back the word after the presentation. As an additional working memory measure, the participant is asked to recall the words after a certain number (ranging from 2-6) of words are presented.
5. Reading Span Test [18]. The Reading Span Test is a measure of working memory capacity that is administered through visual modality. Participants read a series of sentences presented a few words at a time on a computer monitor and then recall the first or last word of each sentence. The test takes about 15 minutes to administer.
6. Letter symbol substitution test [19]. This is a visually administered substitution test that measures processing speed and working memory. The key gives the numbers 1 to 9, each paired with a different letter. Test items are printed beneath the key. Participants are required to replace the randomized letters with the appropriate digit indicated by the key. The test takes less than 5 minutes to administer.

Experiment 2: **three groups of older participants with hearing loss (n=8 for each group), who will be tested in two sessions.** Each participant will receive two out of the three test conditions (auditory unamplified, auditory amplified, and visual) for cognitive test and speech recognition tests. The assignment of the test conditions and test versions is randomized.

Procedures in Session 1 (duration: 2 hours)

Hearing tests, vision screening, and cognitive testing (Test 1, 2 and 3) are screening procedures used for determining the eligibility of the participant. If the participant fails the screening, he/she will be informed immediately at the end of the screening. No research data will be collected after that point. They will not be compensated for the time they have spent on screening tests. If subjects provide authorization, the lab will keep contact information and screening results via the optional element of the consent. However, if they do not provide this authorization, their screening results and identifiable information will be destroyed.

7. Hearing tests

4) Case history: Participants will be asked questions about their hearing and health history.

5) Otoscopic exam: Participants will undergo a brief evaluation of their ear and ear canal with an otoscope.

6) Hearing test. All subjects will undergo hearing testing, where soft tones are presented through earphones and the subject is asked to respond whether s/he has heard the tone by pressing a button. This is a standard clinical test.

8. A vision screening will be administered using a Snellen chart to verify the participant can read all computer displays.

9. The Dementia Rating Scale (DRS-II) assessment will be used to screen for dementia. The DRS-II is a 144-point instrument used in clinical and research settings for the detection, differential diagnosis, and staging of dementia [13]. It measures attention, orientation, word fluency, motor initiation and perseveration, visuospatial construction, conceptualization, and memory, which are organized into five domain subtests (Attention, Initiation/Perseveration, Construction, Conceptualization, and Memory). Test items are arranged hierarchically, and full credit is given to a section if the individual answers the initial items correctly. Administration time usually takes 20–30 minutes.

Speech recognition test. In order to confirm the predicted effect that speech stimuli are perceived better with amplified and visual presentation, two speech recognition tests are included in

this protocol: word recognition and sentence recognition. For both speech recognition tests, three test conditions (auditory unamplified, auditory amplified, and visual) will be created. The tests will be administered to each older individual using two (out of the three) test conditions. Each participant group will be assigned to a combination of two test conditions (i.e., Group 1: auditory unamplified, auditory amplified; Group 2: auditory amplified, visual; Group 3: auditory unamplified, visual). The first administration will happen in the first session and the second one in the second session, with the order counterbalanced.

- a) Word recognition: NU-6 Word List. A word list of 50 words will be presented to the participant either visually or aurally depending on the test condition assignment. The participant will be instructed to repeat back the word after the presentation. As an additional working memory measure, the participant is asked to recall the words after a certain number (ranging from 2-6) of words are presented.
- b) Sentence recognition: PRESTO sentences [15]. A sentences list of 18 sentences will be presented to the participant either visually or aurally depending on the test condition assignment. The participant will be instructed to repeat back the sentence after each presentation.

10. Cognitive test. The Montreal Cognitive Assessment (MoCA) [16] will be used to obtain a comprehensive measure of older individuals' cognitive abilities. The same three test conditions (auditory unamplified, auditory amplified, and visual) will be created for the MoCA. This test will be administered to each older individual using two test conditions with the following combination: Group1 with Amplified-Visual, Group2 with Amplified-Unamplified, Group3 with Unamplified-Visual. The first administration will be in the first session and the second administration in the second session. The condition assignment will be kept consistent to the speech recognition tests.

Procedures in Session 2 (duration: 2 hours)

1. Speech recognition. The second administration of speech recognition tests (words and sentences) will happen in Session 2. A second test modality that is different from what was done in the first session will be used (could be one among the three: auditory unamplified, auditory amplified, and visual). For example, if auditory amplified was done in visit 1, visual could be the test administration modality for visit 2.
2. Cognitive test. The second administration of cognitive test (MoCA) will happen in Session 2. A second test condition that is different from what is done in the first session will

be used (could be one among the three: auditory unamplified, auditory amplified, and visual).

3. Working Memory tests. As mentioned before, in order to capture individual differences in responding to verbal and visual test modalities, we will use three working memory tests to measure verbal and visual working memory.

- a) Word Auditory Recognition and Recall Measure (WARRM) [17]. The WARRM is a measure of working memory capacity that is administered through auditory modality. Participants hear one word at a time and repeat back the word immediately. At the end of each set that contains a few words, they are asked to recall the words they heard in the set. The test takes about 10-15 minutes to administer.
- b) Reading Span Test [18]. The Reading Span Test is a measure of working memory capacity that is administered through visual modality. Participants read a series of sentences presented a few words at a time on a computer monitor and then recall the first or last word of each sentence. The test takes about 15 minutes to administer.
- c) Letter symbol substitution test [19]. This is a visually administered substitution test that measures processing speed and working memory. The key gives the numbers 1 to 9, each paired with a different letter. Test items are printed beneath the key. Participants are required to replace the randomized letters with the appropriate digit indicated by the key. The test takes less than 5 minutes to administer.

4. Study timelines.

- a) This study requires 1 visit of 2 hours (for young participants) and 2 visits of 2 hours each (for older participants) to the Hearing Aid Lab (room 1-451 of the Frances Searle building). Prior to enrolling and signing the consent form for study participation, subjects will have screening tests. This will be agreed to by the participant with a screening consent form. This preliminary screening test takes approximately 30 minutes (for younger participants) and 60 minutes (for older participants). If a participant is qualified to participate based upon their screening test, they will be enrolled in the study via the full study consent form and proceed with study tasks that fill the balance of visit 1 for a total visit time of 2 hours.
- b) The estimated time span of this project will be two years.

A description of this clinical trial (#NCT03402932) will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify a participant. At most, the website will include a summary of the results.

Participants can search this website at any time.

The data of this study will be scores of speech recognition and cognitive tests, and audio and video recordings that contain only non-identifiable information. The data will be stored on the Northwestern server.

Each subject will receive a study code and that code will be used for all study data. The link between the subject name and code are password-protected and stored on a HIPAA-approved server with server security managed by Northwestern School of Communication computer support staff. All research staff will be trained in appropriate Human Subjects protection procedures, including confidentiality.

6.0 Incomplete Disclosure or Deception:

N/A

7.0 Recruitment Methods:

Subjects will be recruited from existing lab subject pool, through study notices on bulletin boards, or if needed from the Communication Research Registry. The Communication Research Registry is a confidential database for individuals and families who would like to continue participating in research housed within Northwestern University's School of Communication. These individuals sign up with the intention of being contacted for various research studies centered on human communication and development. Subjects who indicate an interest in participation will be contacted by an investigator, either by phone or email as preferred by the potential subject; and informed of study procedures, including inclusion criteria and time required for participation.

8.0 Consent Process:

Prior to enrollment potential participants will have hearing, cognitive and visual screening tests with authorization by a screening consent form. These tests will allow us to exclude

potential participants from enrolling in the study who are ineligible based upon their hearing/vision or cognitive status. If participant is eligible based upon their screening results, they will be enrolled in the study with separate consent. These 60 minute tests are built into the study design of visit 1 tasks, and do not require additional visits. If a participant is not eligible to participate based upon the screening consent they can authorize future contact with the consent's optional element as well as authorize the lab to retain the screening results.

All subjects will provide their consent to the screening tests and to study procedures to the investigator or her research assistants. These processes will take place in the Hearing Aid Laboratory, prior to any research procedure taking place. All consent forms are stored in a locked file cabinet drawer within the Hearing Aid lab (a locked laboratory). An unlimited amount of time will be provided to the participant to ensure they have adequately reviewed the consent form and all questions have been addressed by study staff. Following the subject's opportunity to read the consent document, study staff will review each section with participant to clarify the study or any procedure, and ensure understanding. Additionally consent forms may be provided to a potential research participant before a study visit is scheduled so they may take extra time to review form with a family member before committing to participation. All participants will receive a copy of their signed consent form.

We will give participants the option of being audio and/or video recorded during this experiment (for both screening and data collection). The objective of this recording is to be able to have internal lab staff reliability discussions to ensure test reliability and accuracy. When recorded, participant anonymity will be maintained (i.e. name is not being said, face is not recorded, hands are being recorded if possible). Participants will document on the consent form whether or not they agree to being recorded, or if recording is not applicable for a specific experiment. Recordings will be stored on the lab server that is password-secured. These recordings will be used by lab staff only and will be destroyed once data analysis is complete.

9.0 Financial Compensation:

Upon completion of this study, subjects will be paid an hourly rate for participation (\$10/hr). They will be paid in cash at the conclusion of each study visit. If a subject decides to withdraw from the study before its completion, s/he will still be paid \$10 per hour for the time spent.

10.0 Audio/Video Recording

The data of this study will be scores of speech recognition and cognitive tests, and audio and video recordings that contain only non-identifiable information. The data will be stored on the Northwestern server. The audio/video recording of the cognitive testing will be taken to ensure scoring accuracy (a second scorer will listen to the audio recording and correct any potential errors). The recording will be destroyed 3 years after the completion of the study.

11.0 Potential Benefits to Participants:

Subjects may benefit from knowledge of their amount of hearing loss, speech recognition and cognitive performances. They will have a chance to ask questions and receive information about options for their hearing loss (outside of the study).

12.0 Risks to Participants:

During the study, the participants may feel bored, tired or frustrated due to the nature of the cognitive tests. As our team is experienced in administering these tests, the boredom and frustration are usually minor, if at all. Frequent breaks will be provided in order to minimize the possibility of experiencing these feelings. In addition, the participant can ask for a break at any time.

Participants may experience uncomfortable or sensitive feelings regarding the personal affect and/or social participation questionnaires. There are no right or wrong answers to these measures. It will be explained to participants that they may take as much time as they need to answer. Participants are given the option or skip any questions they do not wish to answer. There is no penalty for unanswered items.

Withdrawal of Participants:

- Participants will be withdrawn from the study if he or she: 1) does not pass the screening tests; 2) does not complete all of the testing protocol.
- The participant will still be paid for the portion of the study that is completed. The incomplete data will be deleted once data analysis is finished.
- The data of the screening tests will be kept if the participant gives consent for doing so. Otherwise, it will be deleted.

13.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

During the consent process a lab member will explain that their identifiable information will not be used. Each participant will receive a study code that will be used for all study data. The only link between identifiable data and a study code will be on a password protected HIPAA-approved server with server security managed by Northwestern School of Communication computer staff.

Before starting a study procedure the lab member will explain the task and reiterate that they are free to stop at any point. During the administration of questionnaires or cognitive testing the tester will remind the subject they can decline to answer any question they feel uncomfortable answering without any negative consequences

- The data includes hearing screening data, cognitive testing results (and audio/video recording), speech recognition performance, and social participation surveys.
- The hearing and cognitive testing results and social survey will be stored in a locked file cabinet in the lab. The audio recording and the speech recognition scores will be stored on a password-secured server that is maintained by Northwestern School of Communication computer staff.
- All the data will be stored for 3 years after completion of the study.
- Only the team members who are CITI trained will have access to any sources of information about the participant, as well as the data collected in this study.
- Cognitive testing data (audio/video recordings) will be reviewed by one of the team members who did not collect the data but serves as a secondary scorer. Meeting will be held periodically to ensure quality of the data.

14.0 Data Sharing:

We will describe our results and data in publications and conference presentations. Data will be de-identified whenever described.

References

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